ELECTRONIC FILING

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Appl. No.	:	10/772,086
Applicant	:	Mo Jafari; David H. Burkett; Edwin P. Mahieu; Brad Kellerman
Filed	:	February 3, 2004
Art Unit	:	3736
Examiner	:	Brian S. Szmal
Title	:	APPARATUS AND METHOD FOR JOINING TWO GUIDE WIRE CORE MATERIALS WITHOUT A HYPOTUBE
Confirmation No.	:	2378
Docket No.:	:	ACSG-67401 (3052C)
Customer No.	:	24201

REASONS FOR PRE-APPEAL BRIEF REQUEST FOR REVIEW

INTRODUCTION

The present invention relates generally to an intracorporeal device such as a guide wire. More particularly, the presently claimed invention is directed towards an apparatus comprising a guide wire including a core having a proximal core section with proximal and distal ends and a distal core section with proximal and distal ends and a weld that does not include a filler material at a joint connecting the proximal core section to the distal core section. Further, the joint connecting the proximal and distal core sections is not covered by a hypotube.

NOTICE OF APPEAL

A Notice of Appeal from the final Office Action of April 26, 2007 is being filed concurrently herewith along with the appropriate fee. Also, a request for a one month extension of time along with the appropriate fee is being filed concurrently herewith. Authorization is provided to charge our deposit Account No. 06-2425 any additional fees that may be due in connection with this filing.

ISSUE ON APPEAL

At issue is whether claims 40, 42-45, 47-50, 52 and 53 should be rejected under 35 U. S. C. § 103(a) as being unpatentable over U.S. Patent No. 5,666,968 to Imran et al. in view of U.S. Patent No. 6,193,706 to Thorud et al. Appellant has argued that there is no motivation to combine the two cited references together, and that even if combined, the references do not teach the claimed invention. The Examiner has found all of Appellant's arguments to be non-persuasive. A copy of the pending claims is attached hereto as Exhibit A. A copy of the drawings is attached hereto as Exhibit B. The Imran et al. patent is attached hereto as Exhibit C and the Thorud et al. patent is attached hereto as Exhibit D.

ARGUMENT

In the final Office action dated April 26, 2007, claims 40, 42-45, 47-50, 52 and 53 were rejected under 35 U.S.C. § 103(a) over U.S. Patent No. 5,666,968 (Imran et al.) in view of U.S. Patent No. 6,193,760 (Thorud et al.). The examiner maintained his rejection of the claims in an Advisory Action mailed July 24, 2007. According to the examiner, Imran et al. and specifically FIG. 3 of Imran et al. discloses a guide wire where the weld joint is not covered by a sleeve. The examiner agrees that Imran et al. fails to disclose that the weld does not include filler material.

The examiner further notes that col. 3, ll. 55-59 of Imran et al. teaches a "butt joint" which implicitly teaches a spot weld. Applicant presumes the examiner has identified and is relying on this teaching as the motivation to combine Thorud et al. with Imran et al.

According to the examiner, Thorud et al. teaches "that a spot weld can be used to weld guidewire sections together."

First, applicant respectfully disagrees with the examiner's statement that Thorud et al. teaches "that a spot weld can be used to weld guidewire sections together." Close inspection of FIG. 4 of Thorud et al. reveals that the resistance or spot weld 32 is between a section of the

guide wire shaft 24 and the sleeve 30, not between a section of the guide wire shaft 24 and another section of the guide wire shaft 15. Indeed, col. 10, ll. 9-10 of Thorud et al. explains that "[h]ollow tubular body 30 is attached to shaft 24 at resistance weld or spot weld 32." Therefore, Thorud et al. gives no indication or suggestion of how to spot weld or resistance weld one section of a guide wire shaft to another section of the guide wire shaft.

Second, Thorud et al. is directed to a snap fit between two shaft sections of a guide wire by use of a snap fit between male and female connectors in a process called "docking." (See, e.g., Thorud et al., col. 5, ll. 6-12; col. 8, ll. 29-31.) There is no interest to permanently weld one section of the guide wire shaft to another.

Third, the examiner relies on the teaching of a "butt joint" in Imran et al. According to Wikipedia (www.en.wikipedia.org/wiki/Welding_Joints) under the topic welding joints, a "Butt joint is considered two pieces of metal welded together at their ends. The word butt refers to the 'end' of the piece of metal ...." Therefore, the expression "butt joint" does not suggest or imply a spot or resistance type weld.

Consequently, the examiner's reliance on "butt joint" as the motivation is invalid. Imran et al. contains no teaching, suggestion, or motivation to replace or modify the FIG. 3, no-sleeve, filler weld joint with a spot or resistance weld of Thorud et al. The only motivation for combining Thorud et al. with Imran et al. came from applicant's own disclosure, which is impermissible use of hindsight.

Conversely, if Thorud et al. is used as the primary reference, it is directed to a snap fit between two sections of a guide wire to dock one to the other. Imran et al. in FIG. 3 teaches omitting the joint sleeve and welding one shaft section to another. Because of its snap-fit docking objective, there is no motivation in Thorud et al. to weld one guide wire shaft section to

another section. Again, there is no motivation to combine the two references except from impermissible hindsight of applicant's disclosure.

Finally, even if Imran et al. and Thorud et al. were properly combinable, the combination still does not teach the claimed invention. Specifically, since Thorud et al. teaches spot welding the sleeve to the shaft (not welding one shaft section to another shaft section), it would be FIG. 2 of Imran et al. that is modified, not FIG. 3. If the sleeve in FIG. 2 in Imran et al. were modified by spot welding, it still would not teach the claimed invention since there is a sleeve covering the joint.

CONCLUSION

In view of all of the above reasons, applicant respectfully contends that the examiner has not established prima facie obviousness. Thus, the 35 U.S.C. §103(a) rejection of the pending claims should be withdrawn and the claims passed to issue.

Respectfully submitted,

FULWIDER PATTON LLP

Dated: August 10, 2007

By: /douglas r. peterson/
Douglas R. Peterson
Registration No. 53,458

Howard Hughes Center
6060 Center Drive, Tenth Floor
Los Angeles, CA 90045
Telephone: (310) 824-5555
Facsimile: (310) 824-9696
Customer No. 24201
189389.1

EXHIBIT "A"

EXHIBIT A

LISTING OF CLAIMS:

1. - 39. (Canceled)

40. (Previously presented) An intravascular guide wire, comprising:

a core having a proximal core section with proximal and distal ends, and a distal core section with proximal and distal ends;

a weld that does not include a filler material at a joint connecting the distal end of the proximal core section to the proximal end of the distal core section of the intravascular guide wire;

wherein the joint is not covered by a sleeve.

41. (Canceled)

42. (Previously presented) The guide wire of claim 40, wherein the weld is accomplished through heat and pressure.

43. (Previously presented) The guide wire of claim 40, wherein the joint further comprises a first shape at the distal end of the proximal core section and a second shape complementary to the first shape at the proximal end of the distal core section.

44. (Previously presented) The guide wire of claim 40, wherein the joint includes no gap in between the distal end of the proximal core section and the proximal end of the distal core section.

45. (Previously presented) An intravascular guide wire having at least two core materials joined together without the use of a hypotube, comprising:

a core having a proximal core section with a proximal end and a distal end, and a distal core section with a proximal end and a distal end;

the distal end of the proximal core section and the proximal end of the distal core section being aligned complementary to one another; and

a welded joint that does not include a filler material disposed between the distal end of the proximal core section and the proximal end of the distal core section of the intravascular guide wire;

wherein the at least two core materials are joined together without the use of a hypotube.

46. (Canceled)

47. (Previously presented) The guide wire of claim 45, wherein the welded joint includes no gap in between the distal end of the proximal core section and the proximal end of the distal core section.

48. (Previously presented) The guide wire of claim 45, wherein the welded joint includes a mass of hardened material.

49. (Previously presented) The guide wire of claim 45, wherein the distal end of the proximal core section and the proximal end of the distal core section abut each other at the welded joint.

50. (Previously presented) An intravascular guide wire, comprising:

a core having a proximal core section with proximal and distal ends, and a distal core section with proximal and distal ends;

means for welding the core sections together that does not include a filler material disposed at a joint in between the distal end of the proximal core section and the proximal end of the distal core section of the intravascular guide wire;

wherein the joint is not covered by a sleeve.

51. (Canceled)

52. (Previously presented) The guide wire of claim 50, wherein the means for welding includes a mass of hardened material.

53. (Previously presented) The guide wire of claim 50, wherein the distal end of the proximal core section and the proximal end of the distal core section abut each other at the joint.

EXHIBIT "B"

FIG. 1

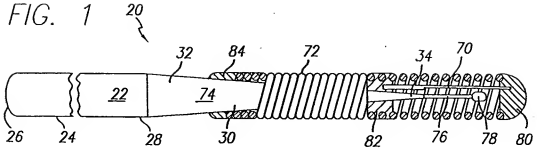


FIG. 2

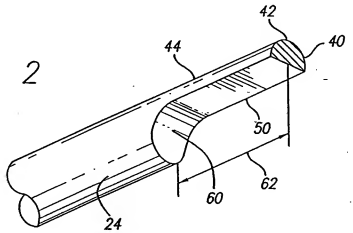


FIG. 3

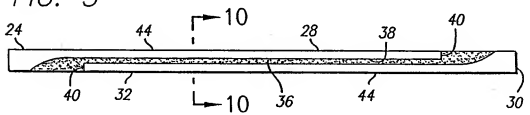
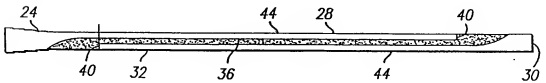


FIG. 4



REPLACEMENT SHEET 2/2

FIG. 5

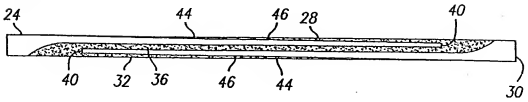


FIG. 6

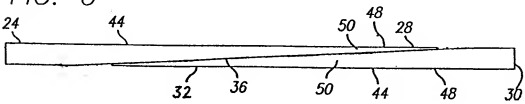


FIG. 7

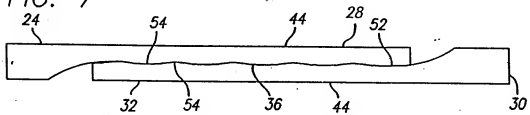


FIG. 8

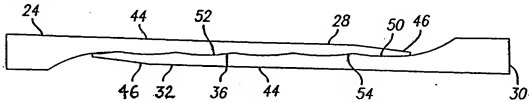
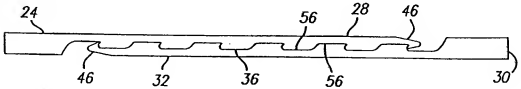


FIG. 9



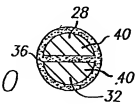


FIG. 10

EXHIBIT "C"

US005666968A

United States Patent [19]

Imran et al.

[11] Patent Number: 5,666,968

[45] Date of Patent: Sep. 16, 1997

[54] **FLEXIBLE GUIDE WIRE WITH EXTENSION CAPABILITY AND GUIDE WIRE EXTENSION FOR USE THEREWITH**

[75] Inventors: **Mir A. Imran**, Palo Alto; **Dennis L. Brooks**, Santa Clara; **Deepak R. Gandhi**, San Jose, all of Calif.

[73] Assignee: **Intelliwire, Inc.**, Sunnyvale, Calif.

[21] Appl. No.: **405,882**

[22] Filed: **Mar. 17, 1995**

[51] **Int. Cl.**[6] **A61B 5/00**

[52] **U.S. Cl.** **128/772**; 118/657

[58] **Field of Search** 128/657, 658, 128/772; 604/95, 280, 281, 282, 283

[56] **References Cited**

U.S. PATENT DOCUMENTS

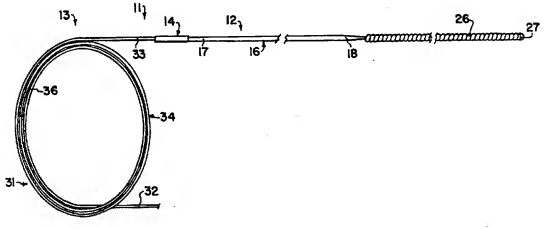
5,238,005	8/1993	Imran	128/772
5,247,942	9/1993	Prather et al.	128/772
5,349,964	9/1994	Imran	128/772
5,357,979	10/1994	Imran	128/772
5,379,772	1/1995	Imran	128/662
5,415,178	5/1995	Hsi et al.	128/772

Primary Examiner—Max Hindenburg
Assistant Examiner—Pamela L. Wingood
Attorney, Agent, or Firm—Flehr, Hohbach, Test, Albritton & Herbert

[57] **ABSTRACT**

A guide wire with extension capability for use in a medical procedure having a guide wire and a guide wire extension. The guide wire comprises a flexible elongate cylindrical member having proximal and distal extremities. A portion of the distal extremity is formed of a material having high torquability and high pushability. The guide wire extension comprises a flexible elongate cylindrical member formed of a shape memory material. A major portion of the flexible elongate cylindrical member of the guide wire extension has a shape memory in the form of a coil so that when it is free it will assume a shape memory coil. A junction is formed between the proximal extremity of the guide wire and the distal extremity of the guide wire extension for connection of the guide wire extension to the guide wire.

11 Claims, 1 Drawing Sheet



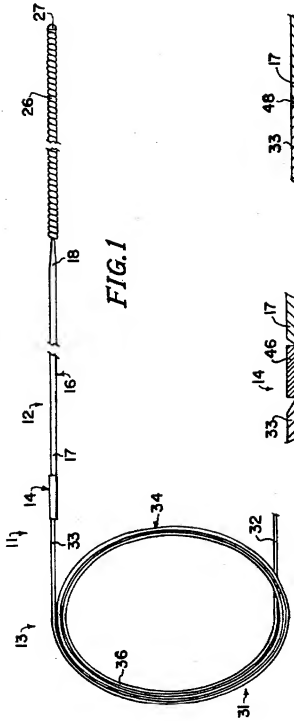


FIG. 1

FIG. 3

FIG. 2

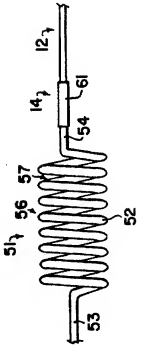


FIG. 4

FLEXIBLE GUIDE WIRE WITH EXTENSION CAPABILITY AND GUIDE WIRE EXTENSION FOR USE THEREWITH

This invention relates to a flexible guide wire with extension capability, and more particularly to such guide wires which are to be used with over-the-wire catheters and particularly over-the-wire balloon catheters used in angioplasty and other procedures and to a guide wire extension for use therewith.

In the past, guide wires utilized in connection with over-the-wire catheters have typically had lengths ranging from 150 to 175 centimeters, although guide wires having lengths ranging up to 300 centimeters have been provided to facilitate the exchange of over-the-wire catheters, the use of such long guide wires has been found to be undesirable. Since they are so long it is necessary to hold and protect the long lengths of extension wires in order that it does not come into contact with anything that is non-sterile. For this reason, separate extension guide wires have been provided which have the capability of being detachably mounted on the proximal extremity of the guide wires. However, these are also disadvantageous because it is necessary to support such extension guide wires in a manner so that they do not touch anything which is non-sterile. Also, in order to avoid the use of extension wires, over-the-wire catheters have been provided which have rapid exchange capabilities eliminating the need for such extension wires. There is still need for a new and improved flexible guide wire which has an extension capability which overcomes the above disadvantages.

In general, it is an object of the present invention to provide a flexible guide wire with an extension capability which includes a guide wire extension having a recoil capability so that when it is free it forms a relatively compact coil that can readily be retained in a sterile environment.

Another object of the invention is to provide a flexible guide wire with an extension capability of the above character in which a guide wire extension can be permanently or detachably mounted on the proximal extremity of the guide wire.

Another object of the invention is to provide a flexible guide wire with extension capability of the above character which can be used by a single person in making an exchange of over-the-wire balloon catheters.

Another object of the invention is to provide a flexible guide wire with extension capability of the above character in which the guide wire extension can be utilized with a conventional guide wire having electrical capabilities.

Another object of the invention is to provide a flexible guide wire with extension capability of the above character in which the guide wire extension has a major portion that is provided with a coil shape memory.

Another object of the invention is to provide a flexible guide wire with extension capability of the above character in which the proximal and distal extremities of the guide wire extension have a straight shape memory.

Another object of the invention is to provide a flexible guide wire with extension capability of the above character which retains its desired torquability and pushability.

Another object of the invention is to provide a flexible guide wire with extension capability of the above character which can be economically manufactured.

Additional objects and features of the invention will appear from the following description in which the preferred embodiments are set forth in detail in conjunction with the accompanying drawings.

FIG. 1 is a side elevational view of a flexible guide wire with extension capability incorporating the present invention and including a guide wire and a guide wire extension in which the guide wire extension has a shape memory coil in which the coil has turns which lie in planes parallel to the longitudinal axis of the guide wire.

FIG. 2 is an enlarged side elevational view in section of the junction between the proximal extremity of the guide wire and the distal extremity of the guide wire extension which provides for detachable mounting.

FIG. 3 is a side elevational view in section of another embodiment of the junction shown in FIG. 2 and showing a permanent connection.

FIG. 4 is a side elevational view of another embodiment of the guide wire extension shown in FIG. 1 in which the turns of the coil lie in planes substantially perpendicular to the longitudinal axis of the guide wire.

In general, the flexible guide wire with extension capability for use in a medical procedure and comprised of a guide wire and a guide wire extension. The guide wire is comprised of a flexible elongate member having proximal and distal extremities and having a longitudinal axis. The flexible elongate member is formed of a material having high torquability and high pushability. The guide wire extension comprises a flexible elongate element having proximal and distal extremities and a longitudinal axis. At least a major portion of the guide wire extension is formed of a shape-memory material. The shape-memory material has a shape memory therein causing said major portion of the guide wire extension to form into a coil when it is free. The coil is adapted to be straightened out when the extension guide wire is in use. A connection is formed between the guide wire extension and the proximal extremity of the guide wire which may be permanent or detachable.

More particularly as shown in FIGS. 1 and 2 of the drawings, the guide wire with extension capabilities 11 incorporating the present invention is comprised of a guide wire 12 and a guide wire extension 13 and junction forming means 14 interconnecting the guide wire 12 and the guide wire extension 13.

The guide wire 12 can be constructed in a conventional manner such as those used in angioplasty procedures. Such guide wires typically can have a length of approximately 175 centimeters and a diameter of 0.014" or 0.018". Guide wires, however, can have sizes ranging from 0.010" to 0.032" and even larger in medical applications other than in angioplasty.

The guide wire 12 can be of a conventional construction. It is in the form of a flexible elongate cylindrical member 16 having proximal and distal extremities 17 and 18. Typically this flexible elongate cylindrical member 16 can be solid and be formed of a suitable material such as stainless steel having a suitable outside diameter, as for example 0.014" or 0.018". Alternatively, the elongate cylindrical member can be in the form of a stainless steel tubular member typically called a hypotube. It can have a wall thickness of 0.002" to 0.003" inches to provide a lumen (not shown) and have a suitable size, as for example 0.012" through which a core wire or mandrel (not shown) of a suitable diameter as for example 0.010" extends from the proximal extremity 17 to the distal extremity 18 of the flexible elongate cylindrical member 16. The distal extremity of the flexible elongate cylindrical member 16 or the core wire (not shown) as is well known to those skilled in the art can be provided with portions of reduced diameter to provide additional flexibility for the distal extremity of the guide wire 12.

A flexible coil spring 26 is mounted on the distal extremity of the flexible elongate cylindrical member 16 by suitable means such as an adhesive. A rounded tip 27 formed of a

suitable material such as solder is provided on the distal extremity of the spring **26**. The spring **26** can have any suitable length as for example a length of 30 centimeters for a guide wire **12** having a total length of 175 centimeters. As explained previously, this guide wire **12** is of a conventional construction and therefore further details of its construction are not given.

The guide wire extension **13** of the present invention consists of a flexible elongate cylindrical member **31** having proximal and distal extremities **32** and **33**. The flexible elongate cylindrical member **31** can have a suitable length as for example 150 centimeters generally corresponding to the length of the guide wire **12** so that the total combined length is at least about 300 centimeters. In accordance with the present invention, the flexible elongate cylindrical member **31** of the guide wire extension **13** is formed of a shape memory material as for example a nickel titanium alloy. The flexible elongate cylindrical member **31** is solid and can have a slightly smaller diameter than the guide wire. Thus for example with a guide wire **12** having a diameter of 0.014" to 0.018", the flexible elongate cylindrical member **31** can have an outside diameter ranging from 0.012" to 0.014". In accordance with the present invention, the proximal extremity **32** and the distal extremity **33** are provided with a straight shape memory as is shown in FIG. **1**, whereas the major portion of the flexible elongate cylindrical member **31** intermediate the proximal and distal extremities **32** and **33** has a coil shape having a diameter ranging from 2.0" to 8.0", so that when the flexible elongate tubular member **31** is free, it will recoil itself into a coil **34** shown in FIG. **1**. As shown, the coil **34** is provided with a plurality of turns **36** with the number of turns being increased with a decreased size for the diameter of the coil and decreased with an increased size in the diameter of the coil. The coil **34** which is formed lies in a plane generally parallel to the longitudinal axis of the guide wire **12**.

Connection means is provided for forming the connection or junction **14** between the distal extremity **33** of the guide wire extension **13** and the proximal extremity **17** of the guide wire **12**. As shown particularly in FIGS. **1** and **2**, this means consists of a sleeve **46** formed of a suitable material such as stainless steel which has one end of the same crimped onto a plunge ground portion **33***a* of the distal extremity **33** of the guide wire extension **13**. Alternatively, an adhesive or solder can be used to fasten the sleeve **46** to the distal extremity **33**. Typically the sleeve **46** should not have an outer diameter which is much greater than the outer diameter of the guide wire **12**. Typically the distal extremity of the guide wire extension **13** will only extend partially into the sleeve **46** so that the plunge ground portion **17***a* of the proximal extremity **17** of the flexible elongate cylindrical member **16** can fit within the other end of the sleeve **46** and be detachably retained therein by cooperative releasable means such as by a friction fit or a thermoplastic adhesive.

Alternatively, as shown in FIG. **3**, the junction **14** can be in the form of a junction **41** which can be in the form of a solder joint or weld which permanently joins the two portions in a butt joint and provides a smooth transition from the guide wire **12** to the guide wire extension **13**.

Another embodiment of the guide wire extension **51** incorporating the present invention is shown in FIG. **4**. It consists of a flexible elongate cylindrical member **52** having proximal and distal extremities **53** and **54**. As with the guide wire extension **13**, the flexible elongate cylindrical member **52** is formed of a shape memory material having the same length and diameter. As shown in FIG. **4**, the proximal and distal extremities **53** and **54** are given a straight shape memory whereas the major portion intermediate the same is formed into a coil **56** having a plurality of turns **57**. Typically the coil **56** would be of a smaller diameter than the coil **34**, because as shown in FIG. **4** the coil is designed so that its axis is parallel to that longitudinal axis of the guide wire extension **51** and the individual turns of the coil lie in planes which are substantially perpendicular to the longitudinal axis. Typically the turns **57** of the coil **56** would be of a smaller diameter than the turns **36** of the coil **34** so that the turns will remain substantially vertical when the coil **56** is lying on a surface. The guide wire extension can be secured to a guide wire **12** in the same manner as the guide wire extension **13**. Thus, by way of example, a sleeve **61** has been provided on the straight shape memory distal extremity **54** and is affixed thereto in the manner described for the sleeve **46**. The sleeve **61** is adapted to be removably attached to the guide wire **12** also in the manner described for the sleeve **46**.

Operation and use of the guide wire with extension capabilities **11** may now be briefly described in conjunction with a conventional angioplasty procedure. Let it be assumed that the guide wire **11** has been positioned in a coronary vessel. While this was taking place, the coil **36** can be resting on the operating table on the drapes over the patient so that it remains in a sterile field with it being unnecessary for nurse or other attendant to hold the same while the guide wire is being advanced into the coronary vessel. Thus, the physician can perform this procedure by himself. If the guide wire extension **13** is permanently attached to the guide wire **11**, the guide wire extension **13** can be stretched out against the force of the shape memory material and the over-the-wire balloon catheter threaded over the extension guide wire and then over the guide wire into the coronary vessel of the patient until the balloon carried by the catheter is disposed in the stenosis on which it is desired to perform an angioplasty procedure. Thereafter in a manner well known to those skilled in the art the balloon of the catheter can be inflated to attempt to increase the flow passage through the stenosis. Let it be assumed that it is desired to thereafter utilize another angioplasty catheter having larger balloon thereon. Keeping the guide wire **11** in place, the first angioplasty catheter is withdrawn over the guide wire **12** and over the guide wire extension **13** by uncoiling the guide wire extension **13**. Thereafter another over-the-wire balloon catheter having a balloon thereon is threaded onto the guide wire extension **13** as it is uncoiled and then advanced into the vessel of the patient over the guide wire **12**, which still remains in position in the stenosis and into the stenosis. Thereafter, the larger balloon carried by the over-the-wire balloon catheter can be inflated to still further increase the blood flow passage through the stenosis. Thereafter, the over-the-wire balloon catheter can be removed in the same manner as the first over-the-wire balloon catheter followed by the removal of the guide wire **11** as well as the guiding catheter which is typically used. Thereafter the cut formed in the femoral artery can be sutured in a conventional manner to complete the procedure.

In the event it is desired to utilize a guide wire with extension capabilities **11** having a detachable guide wire extension, the detachable connecting means shown in FIG. **2** utilized to secure the guide wire extension **13** to the guide wire **12** after which the guide wire **11** can be advanced in the patient in the vessel of the patient in the manner hereinbefore described and used as hereinbefore described.

The embodiment of the guide wire extension **51** shown in FIG. **4** can also be utilized in the same manner as the guide wire extension **13** shown in FIG. **1** with the coils in both embodiments being readily extendable so that an over-the

wire balloon catheter can be passed over the same. Guide wire extensions **13** and **51** are formed in such a manner so that they take very little space in their coiled form and can be readily placed in a sterile field near the patient so that they need not be held by an attendant during the procedure making it possible for a single person to perform the procedure. The coils have sufficient strength in their memory so that they will return or recoil to the recoiled positions as shown in FIGS. **1** and **4** when they are free and lying on a generally planar surface. This is particularly advantageous in that there is not an unnecessary length of wire which the physician performing the procedure needs to keep out of the way and keep in a sterile field.

With such a guide wire with extension capabilities, a conventional guide wire having good torquability and pushability can be retained while still providing a guide wire extension which has the unique capabilities of the present invention of having a shape memory which causes it to return or recoil into a coiled configuration that requires little space and which can lie on a relatively planar surface in a sterile field adjacent the patient so that it is ready for use.

As disclosed previously, the guide wire with extension capabilities can have the guide wire extension permanently attached so that it can be sterilized by the manufacturer and be ready to use. The coil which is formed in the guide wire extension will not affect the torquability of the guide wire, nor will it affect the conventional characteristics of the guide wire **12**. All that is done is that the extension guide wire has been provided with a shape set to prevent it from falling off the operating table and touching non-sterile surroundings. By having the guide wire with extension capabilities utilizing a conventional guide wire, the pushability and torquability as well as trackability of existing guide wires can be retained while still obtaining the advantages of the guide wire extension utilized disclosed herein.

Although the guide wire with extension capabilities **11** has been disclosed as being provided without electrical capabilities, it should be appreciated that the same concepts can be utilized with guide wires having electrical capabilities. For example, as disclosed in U.S. Pat. No. 5,238,005, steering of the distal extremity of the guide wire can be provided. A guide wire having such capabilities in place can have the electrical connections removed and a guide wire extension **13** of the type hereinbefore described connected to the same and utilized for exchanging over-the-wire balloon catheters in the manner hereinbefore described. Similarly, other electrical guide wires can be provided such as those disclosed in U.S. Pat. No. 5,349,964 having a current shunt, electrical guide wires such as disclosed in U.S. Pat. No. 5,357,979 having current controlled adjustable stiffness and adjustable bend locations, and electrical guide wires such as disclosed in U.S. Pat. No. 5,379,772 having forward-looking ultrasonic imaging capabilities. All of the guide wires of this type can utilize a guide wire extension incorporating the present invention.

The guide wire extension of the present invention is also advantageous in that it is relatively simple in construction and can be readily and economically manufactured.

What is claimed:

1. A guide wire assembly with extension capability for use in a medical procedure in a body comprising a guide wire and guide wire extension, said guide wire comprising a flexible elongate member having proximal and distal extremities and a longitudinal axis, at least a portion of the distal extremity being formed of a material having high torquability and high pushability, said guide wire extension comprising a flexible elongate member formed of a shape memory material and having a major portion thereof having a shape memory in the form of a coil so that when it is outside the body will assume its shape of a shape memory coil and means for forming a junction between the proximal extremity of the guide wire and the distal extremity of the guide wire extension.

2. A guide wire assembly as in claim **1** wherein the proximal and distal extremities of the guide wire extension are provided with a straight memory.

3. A guide wire assembly as in claim **1** wherein the coil has turns which lie in a plane which are parallel to the longitudinal axis of the guide wire.

4. A guide wire assembly as in claim **1** wherein the turns of the coil lie in planes which are generally perpendicular to the longitudinal axis of the guide wire.

5. A guide wire assembly as in claim **1** wherein said means forming a junction is in the form of means forming a permanent connection between the guide wire and the guide wire extension.

6. A guide wire assembly as in claim **1** wherein said means forming a junction is comprised of a sleeve and wherein the distal extremity of the guide wire extension and the proximal extremity of the guide wire are disposed in the sleeve and cooperative releasable means carried by the sleeve engaging the proximal extremity of the guide wire for removably retaining the guide wire within the sleeve.

7. A guide wire assembly as in claim **6** wherein said sleeve is affixed to said guide wire extension.

8. A guide wire extension for use with a guide wire having proximal and distal extremities comprising a flexible elongate member having proximal and distal extremities, said flexible elongate member being formed of a shape memory material and having a major portion thereof having a shape memory in the form of a coil so that when the extension guide wire is free, said major portion will assume the shape of a shape memory coil.

9. A guide wire extension as in claim **8** wherein the proximal and distal extremities of the flexible elongate member are provided with a straight memory.

10. A guide wire extension as in claim **8** wherein said coil has turns which lie in planes that are parallel to the longitudinal axis of the guide wire extension.

11. A guide wire extension as in claim **8** wherein said coil has turns which lie in planes that are generally perpendicular to the longitudinal axis of the guide wire extension.

* * * * *

EXHIBIT "D"

US006193706B1

(12) **United States Patent**
Thorud et al.

(10) **Patent No.: US 6,193,706 B1**
(45) **Date of Patent: *Feb. 27, 2001**

(54) **GUIDEWIRE EXTENSION SYSTEM WITH TACTILE CONNECTION INDICATION**

(75) Inventors: **Michael S. Thorud**, Chanhassen; **Robert L. Assell**, Mendota Heights; **Victor R. Blackledge**, Cologne, all of MN (US)

(73) Assignee: **Lake Region Manufacturing Co., Inc.**, Chaska, MN (US)

(*) Notice: This patent issued on a continued prosecution application filed under 37 CFR 1.53(d), and is subject to the twenty year patent term provisions of 35 U.S.C. 154(a)(2).

Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **08/699,895**

(22) Filed: **Aug. 16, 1996**

Related U.S. Application Data

(63) Continuation-in-part of application No. 08/220,902, filed on Mar. 31, 1994, now Pat. No. 5,546,958.

(51) **Int. Cl.**[7] **A61M 25/16**

(52) **U.S. Cl.** **604/533**; 604/538; 604/103.04

(58) **Field of Search** 128/772, 657; 604/95, 104, 280, 281, 282, 283, 103.04, 103.08, 103.09, 107, 109, 533, 534, 535, 538; 600/585, 434

(56) **References Cited**

U.S. PATENT DOCUMENTS

4,149,534	4/1979	Tenczar .	
4,402,682	9/1983	Garver, Sr. et al. .	
4,402,691	9/1983	Rosenthal et al. .	
4,538,622	9/1985	Samson et al. .	
4,569,347	2/1986	Frisbie .	
4,687,470	8/1987	Okada .	
4,790,825	12/1988	Bernstein et al. .	
4,827,941	5/1989	Taylor et al. .	
4,846,193	7/1989	Tremulis et al. .	
4,875,489	10/1989	Messner et al. .	
4,922,923	5/1990	Gambale et al. .	
4,966,163	10/1990	Kraus et al. .	
5,109,867	5/1992	Twyford, Jr. .	
5,113,872	5/1992	Jahrmarkt et al. .	
5,117,838	6/1992	Palmer et al. .	
5,139,032	8/1992	Jahrmarkt et al. .	
5,188,621	2/1993	Samson .	
5,197,486	3/1993	Frassica .	
5,246,009	9/1993	Adams .	
5,247,942	9/1993	Prather et al. .	
5,271,415	12/1993	Foerster et al. .	
5,339,833	8/1994	Berthiaume et al. .	
5,497,782	3/1996	Fugoso .	

Primary Examiner—Anhtuan T. Nguyen
(74) *Attorney, Agent, or Firm*—Michael Best & Friedrich LLP; Grady J. Frenchick

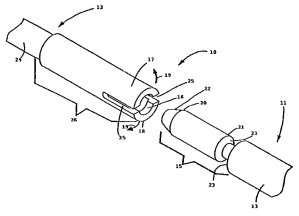
(57) **ABSTRACT**

A guidewire extension system including a guidewire and an extension wire is disclosed. The system includes female and male connector segments located on the proximal end of the guidewire or the distal end of the extension wire. The hollow female connector segment, in one embodiment, includes a radial lip which intersects with at least one, i.e., one or more, lateral slots. The male connector segment includes an external groove. When the male connector is inserted into the female connector segment, the slots are expanded and the lip snaps into the groove providing a tactile indication that connection is completed.

No restriction or frictional fit is created. The guidewire and extension wire are freely rotatable with respect to each other and can be multiply connected and disconnected.

Methods of catheter exchange with tactile indication of guidewire extension wire connection are disclosed.

19 Claims, 15 Drawing Sheets



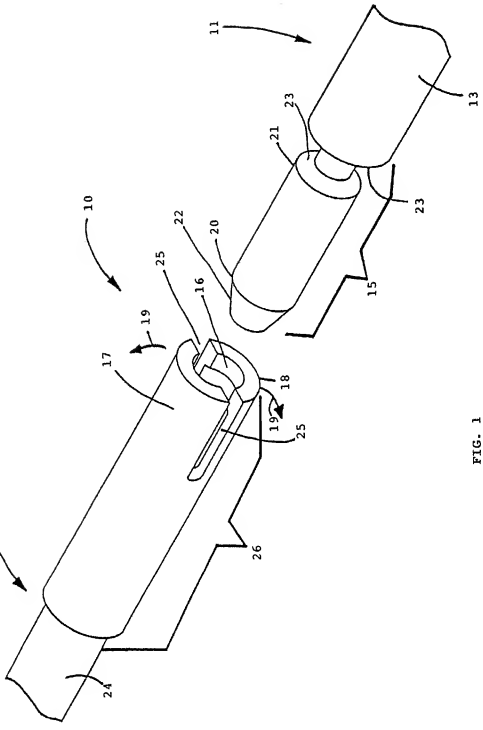


FIG. 1

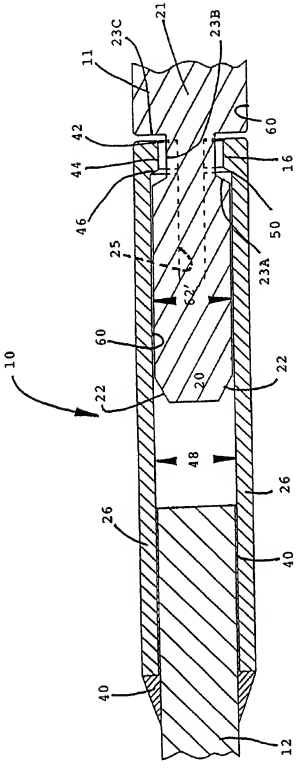


FIG. 2

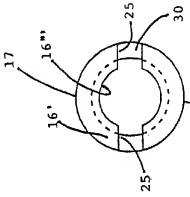


FIG. 3A

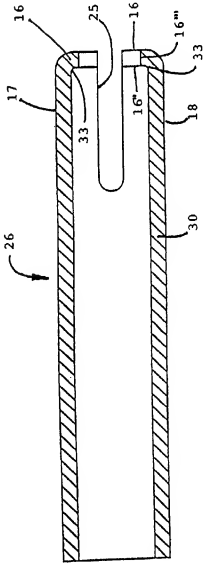


FIG. 3

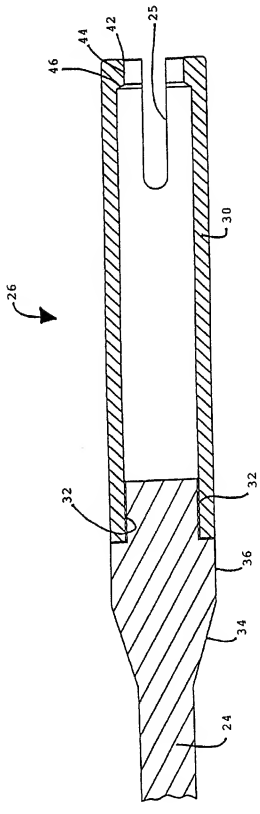


FIG. 4

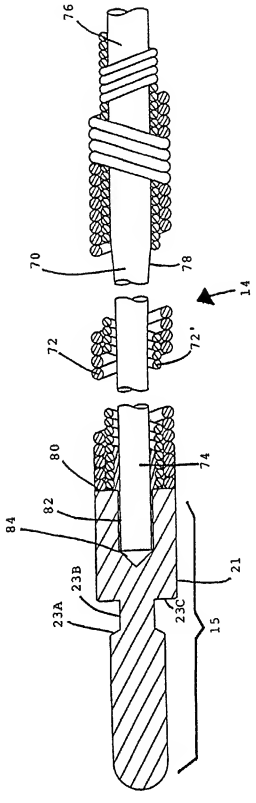


FIG. 5

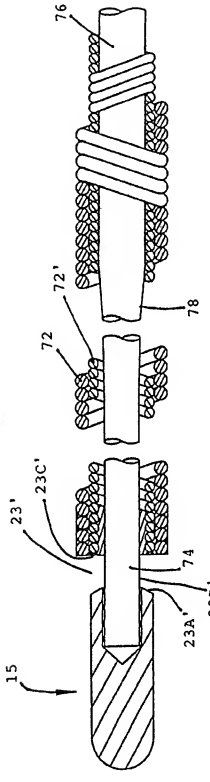


FIG. 6

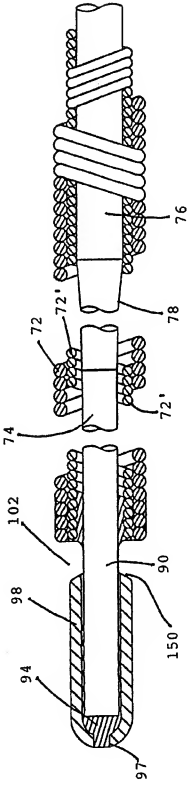


FIG. 7

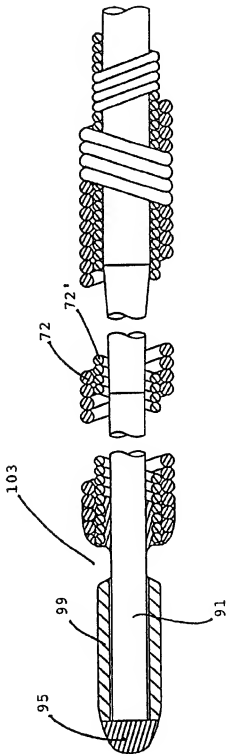


FIG. 8

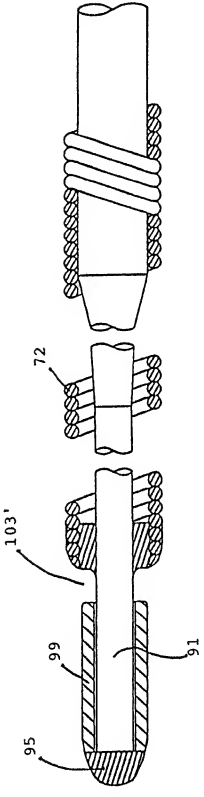


FIG. 8A

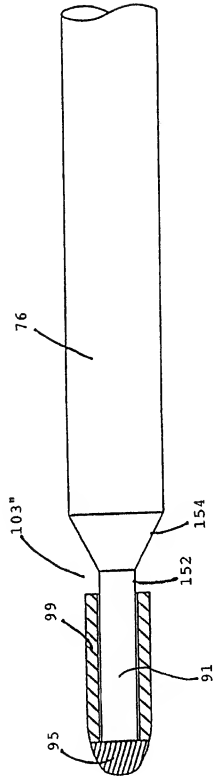


FIG. 8B

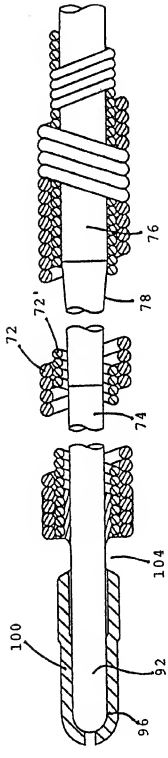


FIG. 9

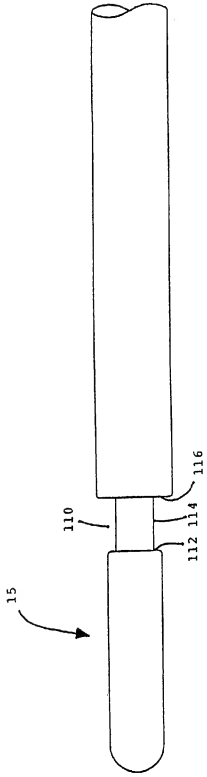


FIG. 10

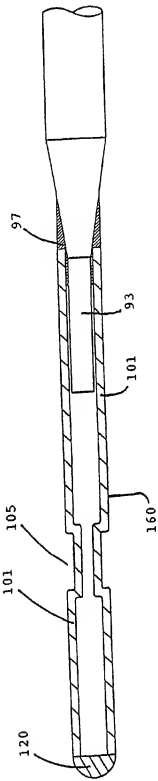


FIG. 11

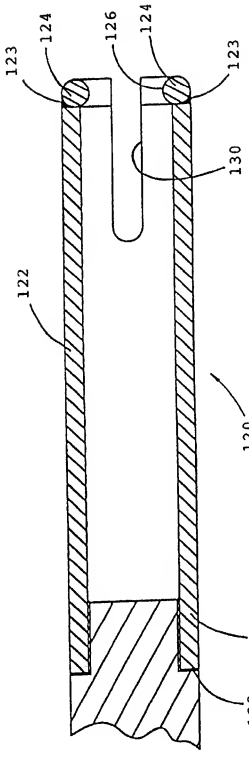


FIG. 12

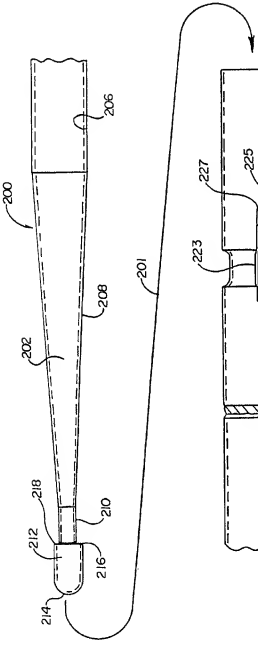

200
202
206
208
201
218
212
210
216
214
223
227
225
204
222
220
229
224
221

FIG. 13

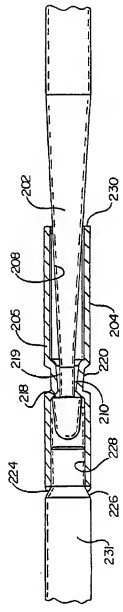

202
230
208
205
204
219
220
218
210
228
224
226
231

FIG.14

GUIDEWIRE EXTENSION SYSTEM WITH TACTILE CONNECTION INDICATION

CROSS-REFERENCE TO RELATED APPLICATION

This application is a continuation-in-part of application Ser. No. 08/220,902 filed Mar. 31, 1994, now U.S. Pat. No. 5,546,958.

FIELD OF THE INVENTION

The present invention relates in general to the field of guidewires. Guidewires are used to position catheters in exploratory procedures, diagnosis, and treatment of various medical conditions. More particularly, this invention relates to a guidewire extension system for connecting or coupling a guidewire, primary or initial wire to an extension or secondary wire during a medical procedure.

BACKGROUND OF THE INVENTION

Guidewires are used in various medical procedures to position medical devices at desired locations within a patient's vascular system. Guidewires, which are steerable, are inserted and maneuvered through the patient's vasculature to a previously chosen location. Once in place, the guidewire provides the means to place a non-steerable device, such as an over-the-wire catheter, at the chosen vascular site. For example, a catheter is slid over the guidewire until the catheter, or some working portion thereof, is positioned within the vasculature at the desired location. Generally speaking, guidewires of a standard length are longer than the non-steerable devices with which they are used to permit independent movement of the device and the wire.

Angioplasty is one interventional procedure where a guidewire is often used. In angioplasty a dilatation catheter having an inflatable balloon structure is used to compress occlusive or blockage material against the sides of a vessel, thereby permitting (ideally) circulation to be reestablished. In preparatory procedures, the site of a vascular restriction, occlusion or stenosis is identified. In the usual procedure, the guidewire is inserted into the patient's femoral artery and maneuvered or steered to the location of the restriction. Maneuvering of the guidewire is facilitated by a video X-ray device which allows the physician to observe the movement of the guidewire's distal tip. The guidewire distal tip generally comprises a radiopaque metal to enhance X-ray viewing. A dilatation catheter then is inserted over the guidewire so that its working segment is located adjacent the restriction. Generally this means that the catheter balloon is positioned adjacent the vascular restriction or blockage.

During a simple angioplasty procedure, the dilatation catheter balloon is inflated to open the restriction, and then is removed along with the guidewire. However, complications sometimes arise which prevent the physician from completing this simple procedure. Occasionally the balloon catheter malfunctions. Sometimes a larger (or smaller) balloon is required further to dilate the vascular restriction, or another device or other type of catheter is needed to remove vascular material. For whatever the reason, the guidewire extension system of this invention is used when the catheter, or other such device, has to be removed and replaced with another device or catheter.

In the usual procedure to exchange catheters, the guidewire is removed from the patient, leaving the catheter in the vascular system. An exchange wire is inserted through the catheter and the catheter removed, leaving the exchange wire in place. The new catheter is inserted over the exchange wire and the exchange wire removed and replaced with the guidewire.

It is desirable to keep the guidewire in the patient's vasculature for various reasons. One reason is that the initial placement of the guidewire requires extensive, time consuming, manipulation. Removal and repositioning of the guidewire would be equally time consuming, possibly requiring a patient to be exposed to additional drugs, radiation, and, in general, additional trauma. It is also of importance that once the guidewire has been steered to a position across a lesion, that the crossed lesion position not be lost by removal of the guidewire. Guidewires removed from a crossed lesion may induce spontaneous vascular restriction or closure making repositioning of the guidewire difficult if not precluded.

In those cases where catheter exchange is desired, the physician would simply prefer to remove the catheter over the guidewire, leaving the guidewire positioned in the patient. However, to permit catheter exchange, a guidewire over which a catheter is to be exchanged must be sufficiently long to allow the physician to grip a portion of the wire as the catheter is being withdrawn over the guidewire. This requires the guidewire to be long enough to provide an external portion longer than the catheter in addition to the guidewire portion remaining in the patient.

Unfortunately, a guidewire of sufficient length to provide suitably long external and internal portions has inferior handling characteristics, thereby making more difficult the steering and maneuvering manipulations needed for guidewire placement. The added length also imposes itself on the usually cramped vascular suite thereby causing distractions from other support activities. It is for these reasons that guidewires are usually only slightly longer than balloon catheters, e.g., 20–50 centimeters longer, and that a much longer exchange wire is used only with exchange procedures.

Illustrating the above, a dilatation catheter has a shaft length in the range of about 120 cm to about 150 cm, a suitable guidewire for such a catheter would have a length in the range of about 150 cm to about 180 cm and an exchange wire would have a length in the range of about 260 cm to about 300 cm. As can be imagined from the above, utilization of an exchange wire in an exchange wire procedure is complicated and time consuming. This invention simplifies catheter exchange and eliminates the need to use an exchange wire.

A recent development involves coupling or connecting a second length of wire, sometimes called an extension wire or secondary wire, to the exposed, proximal end of a positioned guidewire. The secondary wire length should be sufficient to allow the catheter to be withdrawn while leaving the primary or lesion-crossing guidewire positioned within the patient's coronary or peripheral vasculature. Various approaches have been suggested for effecting the attachment of an extension wire to a guidewire.

In one approach, such as that described in U.S. Pat. No. 4,922,923 to Gambale et al., a guide wire and an extension are joined together by crimping. A special crimping tool is disclosed in the Gambale et al., '923 patent. A drawback of this approach is that once the wires have been crimped, the connection therebetween is substantially permanent, and the extension wire cannot be detached from the guidewire except by severing it, e.g., by cutting.

Instead of crimping the guidewire to the extension wire, attempts have been made to engage the extension wire to the

guidewire frictionally. Such attempts are described, for example, in U.S. Pat No. 5,113,872 to Jahrmarkt et al., and related U.S. Pat No. 5,117,838 to Palmer et al. These two patents disclose a guidewire extension system in which the distal end of the extension wire comprises a small diameter tube in which there is disposed a small diameter, open pitch, flat wire coiled spring. The proximal end of the guidewire has a reduced diameter portion which is inserted into the tube assembly to complete the connection. The reduced diameter proximal end of the guidewire is slightly larger than the internal diameter of the coiled spring of the extension wire, thereby creating a frictional engagement when one is inserted into the other. Palmer et al. disclose the utilization of a swivel joint for minimizing twisting of the extension guidewire when connecting or disconnecting it from the extension wire. A device as described in these two patents would be very difficult to manufacture reliably and apparently requires an alignment tool to ease insertion.

U.S. Pat No. 4,875,489 to Messner et al., discloses an extendable guidewire in which concentric tubular segments are secured to one or the other of the sections to be connected. The inner tubular segment has a longitudinal slot therein which permits it to expand when a cooperating male portion is inserted therein. The outer tubular member of the connector assembly restricts the expansion of the inner tubular member as the male portion is inserted therein.

U.S. Pat. No. 4,846,193 to Tremulis et al., disclose a guidewire having first and second telescopically extendable sections movable between axially extended and retracted positions. No disengagement of the guidewire and extension wire is disclosed.

U.S. Pat. No. 4,966,136 to Kraus et al., discloses an internally threaded female connection member secured to the distal end of the extension wire. The internally threaded female connection member is disclosed to be freely rotatable with respect to the extension wire with securement thereto by means of a collar. The body of the extension wire has a distal enlargement which cooperates with the collar to permit it to be freely rotated. The female connection member of the extension wire cooperates with a threaded male portion located on the proximal end of the guidewire. The mechanism disclosed by Kraus et al., requires the difficult step of threading the segments into each other. Threading pieces having the diameters of a guidewire and an extension wire into each other can be difficult to accomplish, especially under operating room conditions.

U.S. Pat. No. 4,827,941 to Taylor et al. discloses a guidewire extension system employing a tubular female connector portion on one wire and a cooperating male portion on the other. The connecting male portion has an effective diameter in one radial dimension which is slightly larger than the inner diameter of the tubular portion. In a preferred practice, the male end portion of the Taylor et al. guidewire has an undulating shape, which, when inserted into the tube creates an interference friction fit.

U.S. Pat. No. 5,247,942 to Prather et al. discloses a guidewire with a swivel. The Prather et al. invention provides for permanent connection of a main part and an extension part. A swivel is included in the system to permit the permanently affixed parts to be rotated with respect to each other to enhance steerability of the main or guidewire segment. The Prather '942 structure has the same drawback as the Gambale '923 system discussed above.

U.S. Pat. No. 5,246,009 to Adams discloses a complicated guidewire assembly utilizing an inner core wire and an outer tube. Torque transmission is an aspect of the Adams invention.

U.S. Pat. No. 5,271,415 to Foerster et al. describes a guidewire extension system comprising a tubular outer body with guidewire and extension wire elements, e.g., helically wound wires, therein. The device of Foerster et al. has the same disadvantage as that of the Kraus et al. '136 patent, i.e., the interconnect step requires threading of the parts into each other. Moreover, the device described by Foerster et al., with brazed wires inside a tubular structure, may be difficult to manufacture.

The guidewire extension systems discussed above all have one or more drawbacks. Some are difficult or tedious or intricate to engage and disengage. Others do not disengage at all. While frictional engagement overcomes the disadvantages of crimping, disengagement may occur too easily. Problems of discontinuity at the guidewire/extension wire connection, e.g., kinking, have been experienced with some systems. Some connector systems are difficult or expensive to build, especially in smaller diameter sizes. Moreover, prior extendable wires for use in coronary angioplasty procedures have been found to be unsuitable in peripheral arteries because the connections are not sufficiently strong. Further, some connections have larger diameters than the rest of the guidewire system. This may cause snagging of, e.g., over-the-wire catheters. It also means that the catheter with which such connection system is used must have a larger internal diameter lumen than would be necessary were a smaller diameter coupler employed.

Accordingly, a principal object of the present invention is to provide a guidewire extension system which is reliable, easy to use, and easy to manufacture, particularly in smaller diameter, coronary sizes.

Another object of the present invention is to provide a guidewire extension system which does not require that either the guidewire or extension wire be rotated when attaching one to the other, i.e., they can be non-rotatively coupled. It is advantageous that the guidewire be held stationary because the guidewire is located within the patient's blood vessel where unnecessary movement can induce trauma. It is also advantageous to have the majority of the length of the extension wire held stationary (e.g., by retention within a carrier structure) during the connection process. Having the extension wire self-contained in a tubular carrier package allows medical personnel to concentrate upon engaging the two wires using the present extension system. An uncontained extension wire is awkward, and thus complicates the process of effecting a guidewire/extension wire union during a medical procedure.

It is a further object of this invention to provide an easily attachable (and reattachable) and easily detachable guidewire extension system which has a readily identifiable tactile sensation, e.g., a "snap", when the system components are affirmatively attached, engaged, or coupled.

It is still a further object of the present invention to provide a guidewire extension system which has substantially the same flexibility and pushability at its connection as that of the remainder of the length of the guidewire. The system provides an advantageously controllable coaxial alignment of the guidewire and extension wire.

It is yet another object of the present invention to provide a unitized guidewire extension system having a substantially uniform, smooth, continuous outer diameter or profile along the guidewire, connector, and extension wire. A smooth, continuous transition in external profile from the distal end of the guidewire to the proximal end of the extension wire, especially over the connector segment, permits an over-the-wire catheter to be positioned by use of the guidewire/

extension wire without getting caught. Methods of manufacturing an extension system of this invention and methods of using a system of this invention also are disclosed.

BRIEF SUMMARY OF THE INVENTION

Briefly, in one aspect, the present invention is an extension system for affirmatively connecting the proximal end of a guidewire to the distal end of an extension wire. In its connected form, the entire structure is sometimes referred to herein as an exchange wire. In one practice, a tactile "snap" is experienced by the user when guidewire/extension wire connection or docking is achieved.

In accordance with one aspect of the present invention, there is provided a coupler for a guidewire/extension wire system, the coupler comprising a male segment and a cooperating female segment. The coupler of this invention permits multiple coupling and decoupling, as needed, of the guidewire/extension wire to which it is attached. The male and female segments are fixedly attached to one or the other of the distal end of the extension wire or the proximal end of the guidewire, and yet the system permits either or both of the guidewire/extension wires to he freely rotated with respect to each other without the structural complication of, e.g., a separate swivel.

The female coupler segment of this invention comprises a hollow, elongate sleeve, the sleeve having opposite ends and a sleeve wall which defines inside and outside sleeve diameters, one of said sleeve ends having an inside diameter such that it can be firmly attached to one of said guidewire or said extension wire. The sleeve wall has an interior reduced diameter zone, segment, bead or lip located (in a preferred practice) approximately midway between the opposite ends of the sleeve. Passing through the reduced diameter zone is at least one, i.e., one or more axial or lateral slots or slits. The slot(s) or slit(s) of this invention pass entirely through the sleeve wall. In a preferred practice of this invention, the aforementioned female coupler segment reduced diameter zone is created hy roll-forming a segment of formable hypotube, i.e., by rolling a bead or dent into the sidewall of a segment of hypotube. In one practice of this invention, a plurality of axial slots pass through the reduced diameter zone. In a further preferred practice, a single axial slot passes through the reduced diameter zone or head, generally perpendicular to its plane or diameter.

The male coupler segment of this invention comprises an elongate member located on the other of the guidewire or extension wire. The elongate member has an exterior surface and opposite ends which are referred to herein, as insertion or leading and following or connection ends, respectively. The insertion or leading end of the elongate member is the first portion of the elongate member to enter the female sleeve in the coupling process. The male coupler segment is affixed to the proximal end of the guidewire or the distal end of the extension wire, as appropriate. Several attachment locations and methods of attachment are discussed below. The exterior surface of the elongate member defines at least a portion of a radial groove and an annular shoulder in the following end, the groove having a diameter which cooperates with the female coupler segment bead so that when said male member is inserted into said female segment, the bead passes or slides along the exterior surface of the male member in a slightly separated position, passes over said shoulder and returns to a non-separated position within the groove or notch. In this manner, the female coupler segment is retained substantially coaxially along the male coupler segment after insertion. Coupling occurs with a tactile sensation that insertion is completed, e.g., with an identifiable "snap."

In a further practice, the outside diameter of the male coupler segment, as defined by its exterior surface, is less than the inside diameter of the female coupler sleeve, leaving an annular space therebetween and precluding a possible restriction or frictional interaction between the cooperating segments.

In yet a further preferred practice, the male member has a tapered insertion end, permitting easy insertion of said male member into the female coupler sleeve.

A guidewire extension system of this invention can be used to connect an otherwise conventional extension wire to a steerable guidewire having a plurality of multifilar, oppositely wound coils. Of course the guidewire also may have only a single coil, depending upon application. For smaller diameter guidewire applications, e.g., 0.014 in. diameter coronary wires, a guidewire core having no coil at all may be used.

In another practice, the female segment is disposed on the distal end of the extension wire and the male segment is disposed on the proximal end of the guidewire.

BRIEF DESCRIPTION OF THE FIGURES

The present invention may be better understood with reference to the detailed description helow and the attached FIGURES wherein like reference numerals designate like features throughout, and wherein:

FIG. **1** is a perspective view of an embodiment of the present invention;

FIG. **2** is a cross-sectional view of the embodiment of the invention of FIG. **1** after the connector segments have been mated;

FIG. **3** is a sectional view of a female connector segment of this invention;

FIG. **3**A is an end view of the segment shown in FIG. **3**;

FIG. **4** is a sectional view showing the structure of an attachment between a female coupler segment of this invention and the extension wire to which it is attached;

FIG. **5** is a partial sectional view of a male coupler segment of this invention;

FIGS. **6**, **7**, **8**, **9** and **11** are partial sectional views of further embodiments of male coupler segments of this invention;

FIG. **10** is a side view of a male coupler segment of this invention.

FIG. **12** is a sectional view of an alternative female coupler sleeve of the present invention.

FIG. **13** is a perspective view of a further embodiment of the invention.

FIG. **14** is a sectional view of the invention of FIG. **13** after its components have been connected.

DETAILED DESCRIPTION OF THE INVENTION

One of the advantages of this invention is that the male member and the female coupler are conveniently coupled and decoupled using insertion and withdrawal forces easily applied by medical personnel. They are not permanently affixed to each other and no restriction or frictional fit is created. Neither of the male nor the female coupler segments are threaded, thereby eliminating the need to create those threads. This also eliminates any need to thread relatively small components into each other during a coupling/decoupling sequence. In application of this invention, no rotation of either part is required in order to achieve coupling and decoupling.

The extent of coaxial alignment at the coupler can be controlled by adjusting the length of the overlap between the male coupler segment and the female coupler segment. For example, if a relatively longer male coupler segment is used, i.e., an elongate member which is relatively longer between its leading end and its groove, then axial alignment of the connected ends of the guidewire/extension wire is more rigidly maintained. Conversely, if a shorter male member (up to and including a substantially spherical ball) and a corresponding sized female coupler segment are used, then the axial rigidity of the overlapped coupler segments will be relatively minimal. Adjustment of guidewire/extension wire overlap at the coupler may produce changes in the "feel" of an extended guidewire to a catheter user.

One skilled in this art will appreciate that there are likely to be a number of structural equivalents to the "lip" and "groove" construction described here. All of such constructions are within the scope of the present invention. For example, instead of a lip on the female coupler segment, one or more dimples or protrusions (or a series or locus of dimples or protrusions) could be machined, stamped, or molded therein. In that embodiment, the male segment would have surfaces, detents, or dents which would cooperate with the dimples to provide a tactile sensation at coupling and to couple the segments. A slide-stop (such as that mentioned in U.S. Pat. No. 5,247,942) could be used if the cooperating surfaces of the slide and stop permitted the slide/stop to be decoupled using decoupling or withdrawal forces in the range discussed below.

It will also be appreciated that a "lip" or bead, as that term is used herein, may be located within the coupler sleeve rather than at one end. In such an arrangement, an intermediate narrow region or lesser diameter segment would be stretched, expanded or moved further within the coupler sleeve to create the tactile sensation of connection as the male member passed therewithin. One or more lateral slots would be utilized and pass through the intermediate narrow region to permit the male member to pass therethrough more easily. As noted above, a preferred practice of this invention is utilization of a single axial slot passing through the bead. The single slot embodiment is particularly preferred for smaller diameter coronary guidewire applications, e.g., guidewire applications where outside diameters in the range of about 0.010 inches to about 0.020 inches, preferably about 0.014 inches to about 0.018 inches are used.

As is shown in FIG. 1, a guidewire extension system **10** embodying features of the present invention has a guidewire or main section **11** which is adapted to be inserted into a patient's vascular system and an extension wire or extension section **12** which can be connected and disconnected to the main section **11**. Connection and disconnection of guidewire **11** and extension wire **12** facilitates catheter exchange without the need for removing the main guidewire section **11** from the patient's vascular system. In the embodiment shown, guidewire section **11** generally comprises an elongated shaft **13** having a distal end (not shown in FIG. **1**) with a male coupler segment **15** located at its proximal end. (The details of a preferred guidewire structure are discussed below.) Shaft **13** optionally may be covered with a polymeric, e.g., polytetrafluoroethylene (PTFE), polyurethane, or other coating (not shown). Single filar coils, multifilar coils, radiopacity markers, or other commonly utilized guidewire structures, may be disposed on shaft **13**. These structures have been omitted from this description of the invention for purposes of clarity.

Extension section **12** has an elongated shaft **24** with a hollow female coupler segment **26** secured to its distal end. Female coupler segment **26** may be fixed to extension wire **24** using techniques well known in this art such as resistance welding, crimping, gluing, soldering, or brazing. Female coupler segment **26** may comprise, for example, a suitably modified section of hypotube brazed to the distal end of an extension wire. Female coupler segment **26** may also be machined from a segment of solid, cylindrical core workpiece. Powder metallurgy techniques also may be used to manufacture female coupler segment **26**.

Also shown in FIG. **1** are the plurality of longitudinal slots **25** and a circular lip **16**. Slots **25** intersect and divide circular lip **16** producing opposite, semicircular tabs **17, 18** which can be radially separated (in the direction of arrows **19**) as male and female segments **15** and **26** are mated. Slots **25** may be machined into coupler segment **26** using conventional grinding and cutting operations or they may be created by any of a number of other known processing techniques including electrical discharge machining. The portion of the shaft **24** proximal to the female member **26** may be covered with, e.g., a polymeric, or other type of coating.

Male connector segment **15** is elongate, having opposite leading or insertion and following ends **20, 21** respectively. In this embodiment, insertion end **20** is tapered (at **22**) to ease the connection process. The exterior surface of male connector segment **15** further defines a radial groove **23**.

FIG. **2** illustrates the detailed interaction between lip **16** and radial groove **23**. FIG. **2** is a cross-sectional view of an embodiment of the invention **10**, shown in FIG. **1**, after the segments have been coupled or "snapped" together. In this embodiment, female coupler segment **26** comprises a section of hypotube which has been brazed (at **40**) to extension section wire **12**. Other methods of securement, e.g., soldering, or gluing, may be employed. As is shown, the glue, solder, or braze zone itself can be employed to provide a smooth transition between the guidewire or extension wire to which the female coupler segment is attached and to the coupler segment itself.

A circular lip **16** of this invention is described in greater detail as follows. Circular lip **16** has a slightly rounded or tapered leading or opening edge **42**, a substantially uniform or single diameter intermediate portion **44** and an angled or rounded interior edge or shoulder **46** which merges (at **50**) to the interior diameter **48** of the hypotube section **26**. Angled interior edge **46** can be, for example, the byproduct of drilling to create interior diameter **48**. Interior edge **46**, in cooperation with the configuration of radial groove **23**, determines at least the magnitude of the force needed to disengage male and female coupler segments **15** and **26**. Other factors such as the material employed, its treatment prior to incorporation into the present coupler, and the precise interaction between the slots and tabs also affect the magnitude of withdrawal forces.

The details of male coupler segment **15** also are shown in FIG. **2**. Male coupler segment **15** (best seen in FIG. **1**) is defined by the configuration of exterior surface **60** of the male segment of the connector system. As was discussed above, male segment **15** has an insertion end **20** and a following end **21**. Insertion end **20**, in this embodiment, is rounded or tapered (at **22**) to provide ease of insertion. The outside diameter **62** of the male segment **15** leads to and defines radial groove **23**. Radial groove **23**, in this embodiment, comprises an angled, radiussed, or perpendicular annular shoulder **23A**, a neck **23B** which has a uniform diameter, and a radial stop surface **23C**. Radial stop surface **23C** can be disposed substantially perpendicularly to the axis of the guidewire extension wire system, as is illustrated,

or it may be filleted or shaped to provide a more rounded stop. As shown, interior edge **46** of female coupler segment **26** is angled so as to be complimentary with and to cooperate with annular shoulder **23**A when lip **16** is lying within radial groove **23**. Radial stop surface **23**C normally controls the extent to which the male and female coupler segments can be engaged, provided the elongate member is short enough to fit completely within female coupler segment **26** and not abut against the extension wire main section. For purposes of orientation, longitudinal slot **25** is shown in phantom.

Three significant observations should be made with respect to the embodiment of FIG. **2**. First, the interior diameter **48** of female coupler segment **26** is larger than the outside diameter **62** of male coupler **15**. This fact means that no restriction or frictional fit is needed for coupling to occur between the male and female segments. The absence of a restriction fit also permits male and female coupler segments **15**, **26** (and therefore the guidewire or extension wire to which they are attached) to rotate freely with respect to each other. In other words, this embodiment of the invention obviates the need for a structure like the swivel of U.S. Pat. No. 5,117,838(Palmer et al.) described above.

The second important observation is that the structure shown in FIG. **2** provides a definite tactile "snap" when the segments are coupled. A sound may also be heard, especially in the larger sized peripheral wires. Whether a sound is generated or not, the tactile sensation of coupler engagement is a significant indicator to the system user that coupling is complete. A small amount of play, as shown in the system illustrated, also permits the physician to move the coupler segments with respect to each other and thereby establish that proper engagement has occurred.

Third, this system permits multiple, affirmative engagement and disengagements of the male and female segments, i.e., multiple catheter exchanges, can be accomplished. This is yet a further advantage over the prior art coupler systems which require permanent connection of the segments.

FIG. **3** is a sectional view of a portion of the female coupler segment **26** of the present invention. FIG. **3**A is an end view of the female coupler segment shown in FIG. **3**. In particular, female coupler segment **26** comprises a hollow tubular body **30** having a substantially circular lip **16** with longitudinal slots **25** therein. Lip **16** has outside and inside edges **16'**, **16"**, respectively, with a radial surface **16'"** therebetween. Lip **16** can be formed by any of several techniques. However, in the embodiment shown, lip **16** was formed by coining a segment of hypotube. This technique of formation is to be contrasted with that of FIG. **2** where drilling, cutting, and grinding steps were employed. It is noted that coining lip **16** tends to create a more rounded or radiussed intersection (at **33**) between tubular body **30** and lip **16** than the same intersection (at **50**) in FIG. **2**. The configuration of the interior intersection between the lip **16** and tubular body **30** will, to some extent, determine connector withdrawal forces.

Slots **25** and lip or tabs **16** define flaps **17** and **18** which move from a substantially parallel, axial, alignment to a slightly oblique alignment (with respect to the system axis) in the coupling process. In the connection step, radial surface **16'"** slides along the exterior surface **60** of the male segment, separating the semicircular flaps **17**, **18** to a slightly opened position. Tubular body **30** biases flaps **17**, **18** toward each other and tends to reduce the radial width of slot **25**. When the connection is made, flaps **17**, **18** return to substantially their original position, a "snap" is heard or felt (or both), and the coupling process is completed. When the coupling process is complete, interior edge **16"** aligns in substantially parallel fashion with shoulder **23**A on male connector segment **15**.

FIG. **4** shows in section the details of one possible approach to attaching female coupler segment **26** to elongated shaft **24**. As was discussed above, in a preferred embodiment, elongated shaft **24** is the distal end of an extension wire but may also be the proximal end of a guidewire or main wire. Hollow tubular body **30** is attached to shaft **24** at resistance weld or spot weld **32**. As is noted above, other techniques for attachment may be used. In FIG. **4** the elongated shaft segment coupled to tubular body **30** is shown to be ramped or tapered at **34**. Taper **34** leads to an extension wire segment **36** which has substantially the same outside diameter as that of hollow tubular body **30**. Elongated shaft **24** has been ground to a smaller diameter than wire segment **36** to enhance flexibility. Taper **34** therefore provides a gentle transition between the extension wire body and tubular body **30** which is particularly desirable. Taper **34** permits a catheter to pass over hollow tubular body **30** (e.g., during a catheter exchange process) without becoming caught on the connector system structure.

FIG. **5** illustrates one possible connection structure between a guidewire proximal end **14** and a male coupler segment **15**. The particular guidewire structure employed is that of a core wire **70** having oppositely wound multifilar coils **72**, **72'** disposed therearound. Core wire **70** has a reduced diameter proximal segment **74** which connects to core wire main section **76** through taper **78**. Coils **72**, **72'** and reduced diameter proximal segment **74** are attached to male coupler segment **15**, e.g., by brazing, at **80** and **82**, respectively. Male coupler segment **15** is brazed to guidewire proximal end **82** at bore **84** which is drilled or machined in the following end **21** of male coupler segment **15**. It is important that there be a smooth transition from male coupler segment **15** to the remaining structure of the guidewire so that a catheter can slide smoothly thereover during an exchange process.

FIG. **6** illustrates another embodiment of the invention wherein groove **23'** comprises a shoulder **23**A', a portion of reduced diameter segment **74** indicated at **23**B' and the proximal end of coils **72**, **72'**indicated at **23**C'. There are many possible ways to construct a groove which will cooperate with a connecting female segment in accordance with this invention.

FIGS. **7**, **8**, **9**, and **11** illustrate variations in construction of a male connecting segment of this invention. The variations illustrated are alternative ways in which the desired external configuration of the male coupler segment can be created. In each of the systems illustrated, a reduced diameter proximal guidewire segment **90**, **91**, **92**, **93**, respectively, is attached (at **94**, **95**, **96**, and **97**, respectively), to elongate male connector segment **98**, **99**, **100**, and **101** respectively. In each instance a groove **102**, **103**, **104**, and **105** is created or defined. FIG. **7** illustrates a coined sleeve that is attached to the wire core **90** by application of glue, solder, or braze through opening **97** on the insertion end of the segment **98**. This procedure keeps annular shoulder **150** clean. FIG. **8** illustrates a plasma ball weld **95** utilized on the insertion end of male connector segment **99**.

FIGS. **8**, **8**A and **8**B illustrate different sized guidewires in which the present invention has been used. For example, the guidewire shown in FIG. **8** would be the structure of a 0.035 in. and **0.038** in. diameter guidewire having two counter-wound spring coils **72**, **72'**. The embodiment of FIG. **8**A has a single spring coil **72** and would be structure employed in a **0.025** in. diameter guidewire.

FIG. 8B is a structure useable for very small diameter, e.g., 0.014 in., guidewires. No spring coils are used. The extreme proximal end of the guidewire is ground to a lesser diameter and groove 103' is defined by elongate male connector segment 99, a reduced diameter segment 152, and taper 154.

FIG. 9 shows a sleeve whicb was crimped (at 96) on the guidewire body core 92.

FIG. 11 illustrates an embodiment where the requisite external configuration of the male segment is externally formed into a segment of hypotube 160. Hypotube 160 then is brazed onto tbe proximal end of the guidewire and a rounded tip 120 is created on the remaining end.

FIG. 10 illustrates an embodiment of the invention wherein the male connector segment external configuration 15 is simply machined into the proximal section of the guidewire, e.g., by centerless grinding. A radial groove or notch 110 defined by surfaces 112, 114, and 116 cooperates with the lip portion of tbe female coupler segment.

FIG. 12 is a sectional view of an alternative embodiment of a female coupler segment 120 of this invention. In FIG. 12 a section of hypotube 122 has a metal ring 124 brazed, soldered or glued (at 123) to its open end. Metal ring 124 has a diameter which is slightly less than the inside diameter of the hypotube 122 and thereby creates a lesser diameter lip 126. As shown, this approach produces a substantially circular lip. Hypotube section 122 then is resistance welded, glued, soldered or brazed to the guidewire or extension wire core (at 128) with which it is associated. Electrical discharge machining or other known fabrication techniques then are used to create lateral slot 130. Alternatively, ring 124 could be fitted inside of hypotube segment 122 to create an inwardly disposed "lip" as is discussed above. Regardless of the location of the lip, as long as the female and male segments overlap sufficiently, kinking at the connection will be reduced.

In FIGS. 13 and 14 there is shown a further embodiment 200 of the coupler system of the present invention. The embodiment shown is particularly useful for smaller diameter, e.g., cardiovascular dimensioned, guidewires/extension wires. Generally speaking, devices to which this embodiment of the invention may be applied will have outside diameters in the range of about 0.010 inches to about 0.020 inches.

In FIG. 13 system 200 comprises a male coupler segment 202 and a hollow female coupler segment 204. Arrow 201 shows the direction of insertion of the coupler segments. Male coupler segment 202 has a first diameter proximal segment 206, leading to a first tapered segment 208 and in turn to a second, smaller diameter segment 210. Distally attached to second diameter segment 210 is a bullet-shaped head 212. Head 212 has a leading or insertion end 214 and a following end 216. Insertion end 214 is of a hemispberical, rounded configuration to reduce insertion force. Following end 216 comprises an annular shoulder 218. In conjunction witb second diameter segment 210 and taper 208, the exterior surface of male coupler 202 defines an elongate groove or attachment zone which fits into female coupler segment 204.

Female coupler segment 204 comprises, in tbis embodiment, a section of hypotube. In hypotube segment 204 there bas been created or fabricated a reduced diameter segment 220. The interior diameter of hypotube segment 204 (not shown in FIG. 13) is proportionately reduced. For example, segment 220 may be a radial bead or dent rolled into the hypotube segment 204 so as to create a reduced interior diameter region. Intersecting bead 220 is a single lateral slot 222. Slot 222 has been cut entirely through hypotube segment 204 from the outside to the inside so as to provide room for bead 220 to expand radially when male segment 202 is inserted into female segment 204. Slot 222 has generally parallel sides 223, 225 and symmetric, radiussed ends 227, 229. Especially for smaller diameter coupler systems, a single lateral slot intersecting bead 220 is preferred. Female coupler segment 204 is, in turn, attached to one or the other of the guidewire or the extension wire 221 at braze 224. As is sbown, the outside diameter of coupler segment 204 is substantially the same as that of the guidewire or extension wire 221 to which it was attached. Thus, ease of catheter use is provided in that a catheter slides over the coupler system without becoming caught at tbe coupler segment-guidewire/extension wire intersection.

FIG. 14 shows the interior details of the system of FIG. 13 in partial section. With male coupler segment 202 inserted into female segment 204, annular shoulder 218, second diameter segment 210 and taper 208 cooperate with reduced diameter segment or bead 220 to create a coupled system. Female coupler segment wall (shown in section and indicated generally at 205) defines those structures. As is shown, an abruptly tapered section 226 and a reduced diameter section 228 (reduced from the diameter of the main section of the guidewire/extension wire 231) are formed on the guidewire/extension wire end 231 to which female coupler segment 204 is attached at braze 224. Further, taper 208 is shown to cooperate with hypotube open end 230 to restrict or control the extent to which the male segment may be inserted into the female segment. Last, a tactile "snap" (and accompanying sound) will be heard as annular shoulder 218 passes through the reduced interior diameter segment 219 defined by bead 220, and the bead 220 abruptly returns or snaps to its original uncompressed diameter.

Insertion and withdrawal forces are always of concern with connector systems of vascular (especially cardiovascular) dimension and are controllable in the practice of this aspect of the invention. Hemispherical bullet-shaped head 212 reduces the forces necessary to couple the male and female segments. The relationship between annular shoulder 218 and the cross-sectional configuration of bead 220 will determine the magnitude of force required to decouple the segments. Generally speaking, the configuration shown in FIG. 14, i.e., a bead having a lesser diameter following edge (at 230) and a larger diameter leading edge (at 232) will substantially increase withdrawal forces. The angular relationship between annular shoulder 218 and the following edge 230 (among other factors) also will determine the magnitude of withdrawal forces.

In light of the above disclosure, one skilled in this art will understand that several techniques may be used to create the inventive structure disclosed. Specifically, bead 220 can be rolled (i.e., roll-formed) into bypotube segment 204. Slot 222 may then be machined or otberwise cut, e.g., via laser, into, through bead 220, to complete this feature of the invention. The male segment can be created by, e.g., centerless grinding, of the end portion of the guidewire/extension wire on which it is located.

The main guidewire section 11 is intended for use in positioning a catheter (not shown) in the vasculature of a patient, and it has a length corresponding to the length of a conventional guidewire for this purpose. Details of typical catheters and guidewires can be found in U.S. Pat. No. 4,538,622 (Samson et al.) and U.S. Pat. No. 4,569,347 (Frisbie). Those patents are incorporated by reference herein in their entirety.

Extension wire **12** is sufficiently long so that when the main guidewire section **11** and extension wire **12** are connected together, the guidewire system or exchange wire **10** has an overall length suitable for catheter exchange without removing the main guidewire **11** from the patient's vascular system. With a catheter having a length on the order of about 65 cm to 175 cm, for example, guidewire **11** would have a length of about 100 to about 200 cm, and extension wire **12** would have a length of about 100 to about 200 cm (or longer).

Shafts **13** and **24** and female segment **26** can be fabricated from essentially any suitable material, such as stainless steel, Elgiloy, or the shape memory alloy referred to as Nitinol (55% Ni-Bal. Ti). Each should have an overall largest diameter which allows, e.g., a dilatation catheter, to pass freely thereover. Preferably, the two shafts **13** and **24** are provided with a smooth transition between them. Either or both of shafts **13**, **24** can be provided with a coating of polymers or elastomers such as PEBAX polyamide, polyurethane, polytetrafluoroethylene (PTFE), or other such material well known to one skilled in this art.

Typical dimensions of the main guidewire section include an outside diameter of the shaft **13** of about 0.009 to about 0.065 inch, an outside diameter of the male insertion segment about 0.006 inch to about 0.050 inch and a length of about 0.025 to about 0.250 inch. The female connector segment has dimensions which generally cooperate with the male segment dimensions and a length of about 0.060 inches to about 1.0 inches and an outside diameter of about 0.009 in. to about 0.065 in. While this invention is particularly applicable to larger diameter guidewires, e.g., 0.038 inches and 0.035 inches, smaller diameter applications, e.g., 0.025 inches or less, down to 0.009 inch diameter wires, are also within its scope. Generally speaking, the ratio of male segment outside diameter to male segment length and female segment inside diameter to female segment length will fall in the range of 1:100 to about 1:1.Having a segment length which is larger than the respective segment diameter tends to keep the wires more axially aligned, thereby minimizing unwanted bending and kinking.

Percutaneous transluminal angioplasty is a medical procedure in which the present invention can be used. In use, the main guidewire section **11** is percutaneously introduced into the vascular system of a patient with a dilatation catheter through the skin by means of an introducer (not shown). The distal tip of the guidewire is advanced beyond the distal tip of the dilatation catheter while the latter is held in place. The main guidewire section **11** is advanced into the selected vessel. The guidewire tip is preferably advanced through the lesion and beyond it, in order to permit the balloon portion of the dilatation catheter to be positioned within the lesion over a more supportive section of the guidewire. Once in position, the main guidewire section **11** is held in place and the dilatation catheter is advanced along it until the inflatable balloon thereof is within the lesion. Male connector segment **15** remains outside the patient's body and outside any adapter which may be connected to the proximal end of the dilatation catheter. If necessary, e.g., to retain a sufficient length of the main guidewire section **11** outside the catheter for the physician to grip, the guidewire and catheter may be advanced together substantially in unison.

To exchange catheters, the main guidewire section **11** is extended by manually snapping the female tubular member **26** onto the male member **15**. When the two guidewire sections are engaged, the dilatation catheter can then be withdrawn from the patient's body over the extended guidewire system.

A new dilatation catheter may then be introduced over the extension section **12** and advanced along the main guidewire section **11** within the patient's body until the balloon crosses the lesion. Once the proximal end of the new catheter has advanced beyond the connection between female member **26** and male member **15**, section **12** can be removed from section **11** by unsnapping the female member **26** by pulling the two sections apart. This can be accomplished without disturbing the position of the main section **11** in the patient's body.

The above description describes utilization of the present invention primarily in coronary angioplasty catheter exchange. It is to be understood that this invention has application in essentially any procedure where a catheter is utilized for diagnostic or interventional applications.

This invention has a number of important features and advantages. The two sections of the guidewire can be connected together whenever a longer, exchange wire is needed, and they can be disconnected whenever the additional length is not required. The two sections of the guidewire may be connected and disconnected (and reconnected, if desired) by the physician by simply "snapping" and "unsnapping" the male segment into or out of the female segment. Subsequent to engagement, the segments can be freely rotated with respect to each other (e.g., to permit the guidewire to be steered) and can easily be disengaged. This can be done as needed, and no special tools are required whether to make the connection or to separate it. Thus, catheter exchange is greatly simplified. This also permits the same guidewire to be repositioned to second and multiple additional vascular sites which then may be treated with different catheters, making the present system very versatile.

As noted in the previous paragraph, a guidewire extension system of this invention can be multiply engaged and disengaged. The present invention therefore permits two or more catheter exchanges, during a medical procedure, without a need to reposition or exchange the main or guidewire. Generally speaking, the ease of disengagement (i.e., the pounds of force needed to disengage an extension wire from a guide wire) has been found to be in the range of about 0.2 to about 5.0 lbs., preferably about 0.3to about 3.0 lbs., and most preferably about 0.7 lbs. to about 2.0 lbs. Factors which affect withdrawal forces include the overall device diameter (withdrawal forces being higher for larger diameter devices), wall thickness of the tube, slot configurations, the materials of which the male and female coupler segments are made, and the relationship between the cooperating surfaces on the male and female coupler segments. The more abrupt or acute the relationship, the higher the withdrawal forces. With reference to FIG. **2**, the more nearly perpendicularly (relative to the axis of the device) shoulder **23A** engages surface **46**, the more difficult withdrawal of male coupler segment from the female coupler segment.

It is apparent from the foregoing that a new and improved extended guidewire system has been provided. While the present invention has been described herein with the male connecting element fixed to the distal end of the main guidewire, and the female member located on the distal end of the extension section, it is obvious that the female connector member and male connector member may be interchanged. Moreover, it will be apparent to those familiar with the art that other modifications and improvements can be made without departing from the scope of the invention as defined by the following claims.

What is claimed is as follows:

1. A coupler for a guide wire/extension wire system, the coupler comprising;

a male segment and

a female segment, wherein the male and female segments are designed to cooperate to couple and decouple a guidewire to an extension wire, each being attached to one or the other of the distal end of the extension wire or the proximal end of the guidewire;

the female segment comprising:

a hollow, elongate sleeve, the sleeve having opposite ends and a sleeve wall which defines inside and outside sleeve diameters,

one of said opposite ends of the sleeve having an inside diameter such that it can be firmly attached to the guidewire or the extension wire,

there being disposed between said ends and being defined by the inside surface of said sleeve wall, a reduced interior diameter zone, the zone having passing therethrough a longitudinally extending slot, the slot being defined by said sleeve wall and passing through said wall;

the male segment comprising:

an elongate member, the elongate member having an exterior surface which defines an outside diameter which is less than said sleeve wall inside diameter, and oppositely disposed insertion and following ends,

the exterior surface of said elongate member defining a groove and an annular shoulder on said following end, said groove having a diameter which cooperates with the reduced interior diameter zone defined by the sleeve wall of the female member so that when said male segment is inserted into said female segment, said female coupler segment is rotatively retained along said male coupler segment with an annular space therebetween, and coupling occurs with a tactile indication that insertion is complete.

2. A coupler according to claim **1** wherein the outside diameter of the elongate member defined by its exterior surface is less than the inside diameter of the female coupler, leaving an annular space therebetween.

3. A coupler according to claim **1** wherein the tactile indication of a "snap" is experienced when the female segment and male member are completely intercoupled.

4. A coupler according to claim **1** wherein the male member has a tapered insertion end, the taper permitting easy insertion of said male member into said female coupler.

5. A coupler according to claim **1** wherein the female segment is disposed on the distal end of the extension wire and the male member is disposed on the proximal end of the guidewire.

6. A coupler according to claim **1** wherein the guidewire comprises a steerable guidewire having a core wire and a helical coil disposed about its distal end.

7. A coupler according to claim **1** wherein the reduced diameter zone is a bead, the slot being disposed substantially perpendicular thereto.

8. A coupler for a guidewire/extension wire system, the coupler comprising:

a male segment and

a female segment, wherein the male and female segments cooperate to couple and decouple a guidewire to an extension wire when the male segment is disposed on the proximal end of the guidewire, and the cooperaung female segment is disposed on the distal end of the extension wire,

the female segment comprising:

a hollow, elongate sleeve, the sleeve having opposite ends and a sleeve wall which defines inside and outside sleeve diameters, one of said ends being attached to said extension wire, there being disposed between said ends,

a reduced interior diameter zone, that zone having passing therethrough,

a longitudinally extending slot, the slot being defined by said sleeve wall and passing through said wall;

the male segment comprising:

an elongate member, the elongate member having an exterior surface which defines an outside diameter which is less than said sleeve inside diameter, and opposite leading and following ends, the exterior surface of said member defining a radial groove and an annular shoulder on said following end, said radial groove having a diameter which cooperates with said reduced diameter zone so that after said male segment is inserted into said female segment is rotatively coupled thereto; and

said male segment is retained within said female segment which an annular space therebetween, and coupling occurs with a tactile indication that insertion is complete.

9. A coupler according to claim **8** wherein the reduced diameter zone is a bead.

10. A coupler according to claim **8** wherein the outside diameter of the male member as defined by its exterior surface is less than the inside diameter of the female coupler, leaving an annular space therebetween.

11. A coupler according to claim **8** wherein the tactile sensation of a "snap" is experienced when the female segment and male member are completely intercoupled.

12. A coupler according to claim **8** wherein the male member has a tapered leading end, the taper permitting easy insertion of said male member into said female coupler.

13. A coupler according to claim **8** wherein the guidewire comprises a steerable guidewire having a plurality of multifilar, oppositely wound coils disposed about its distal end.

14. A method of coupling a main wire and an extension wire, one or the other of said main wire or said extension wire having a hollow, cylindrical female coupler segment, the other of said main wire or said extension wire having an elongate male segment, the method including the steps of:

providing a main wire having a coupler segment on the proximal end thereof, the coupler segment comprising a hollow, cylindrical female coupler segment or an elongate male coupler segment;

providing an extension wire having a coupler segment on its distal end, the coupler segment comprising a hollow cylindrical female coupler segment or an elongate male coupler segment;

coupling the main wire and the extension wire by inserting the male coupler into the female coupler until a tactile sensation indicates coupling has been completed, the coupler segments being rotatable with respect to each other and defining an annular space therebetween; and

withdrawing the male segment from the female segment to decouple the main wire from the extension wire.

15. A method according to claim **14**, wherein the decoupling step is accomplished by application of a decoupling force in the range of about 0.2 pounds to about 5 pounds.

16. A method according to claim **14** wherein the decoupling step is accomplished by application of a decoupling force in the range of about 0.3 to 3.0 pounds.

17. A coupler for a guidewire/extension wire system, the coupler comprising:

a male segment and

a female segment, wherein the male and female segments cooperate to couple and decouple a guidewire to an extension wire when the male and female segments are each attached to one or the other of the distal end of the extension wire or the proximal end of the guidewire,

the female segment comprising:

a hollow, elongate sleeve, the sleeve having opposite ends and a sleeve wall which defines inside and outside sleeve diameters, one of said ends having an inside diameter such that it can be attached to one of said guidewire or said extension wire, there being disposed between said ends and being defined by said sleeve wall,

a reduced interior diameter zone, the zone having passing therethrough,

one or more longitudinally extending slots, being defined by said sleeve wall and passing through said wall,

the male segment comprising:

an elongate member, the member having an exterior surface, and oppositely disposed insertion and following ends, the exterior surface of said member defining a groove and an annular shoulder on said following end, said groove having a diameter which cooperates with said reduced interior diameter zone so that when said male segment is inserted into said female segment,

said female coupler segment is retained along said male coupler segment and is rotatively coupled thereto, coupling occurs with a tactile indication that insertion is complete decoupling occurs by application of withdrawal forces in the range of about 0.2 to about 5.0 pounds, whereby said male segment and said female segments are conveniently coupled and decoupled.

18. A coupler according to claim 17 wherein the outside diameter of the elongate member defined by its exterior surface is less than the inside diameter of the female coupler, leaving an annular space therebetween.

19. A coupler according to claim 17 wherein the tactile indication of a "snap" is experienced when the female segment and male member are completely intercoupled.

* * * * *